IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

CHERYL MOULTRIE and PETER MOULTRIE, Plaintiffs, vs COLOPLAST CORP. and COLOPLAST MANUFACTURING US, LLC, Defendants.	)	Civil Action No. 18-231 Magistrate Judge Dodge

MEMORANDUM OPINION

Plaintiffs, Cheryl Moultrie ("Mrs. Moultrie") and her husband, Peter Moultrie, bring this product liability action asserting claims of strict liability and negligence against Defendants Coloplast Corp. and its wholly-owned subsidiary, Coloplast Manufacturing US, LLC (together, "Coloplast"). Plaintiffs' claims arise out of serious injuries that Mrs. Moultrie allegedly sustained as a result of the implantation of Coloplast's product, a prescription-only surgical mesh implant known as the Aris Transobturator Sling System ("Aris"), to treat her stress urinary incontinence.

Currently pending before the Court for disposition is Coloplast's Motion for Certification of Interlocutory Appeal (ECF No. 98). For the reasons that follow, the motion will be denied.

I. Relevant Procedural History

On July 31, 2019, Coloplast moved for summary judgment (ECF No. 63). With respect to Plaintiffs' strict liability claims (Counts I and II of the Complaint), it argued that these claims were barred pursuant to comment k of the Restatement (Second) of Torts § 402A.

On March 16, 2020, the Court issued a Memorandum Opinion and Order (ECF Nos. 93 and 94), granting in part and denying in part Coloplast's motion for summary judgment.

Coloplast's motion was denied with respect to the strict liability claims that Plaintiffs are pursuing.[1]

In its motion for summary judgment, Coloplast cited a number of federal district court cases which predicted that the Pennsylvania Supreme Court would hold that prescription medical devices should be excluded from strict liability claims pursuant to comment k of § 402A. However, the Court concluded that the better-reasoned decisions—which involved the product at issue in this case—are those which conclude that extending comment k (which addresses prescription drugs)[2] to the category of medical devices "requires an assessment and balancing of policies best left to the General Assembly," as the Pennsylvania Supreme Court indicated in *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 382, 396 (Pa. 2014). *See also Lance v. Wyeth*, 85 A.3d 434, 452 n.21 (Pa. 2014).

Thereafter, Coloplast filed the pending motion (ECF No. 98), which has been fully briefed (ECF Nos. 102, 105).

II. Discussion

A. Standard of Review

The standard for allowing an interlocutory appeal is as follows:

> When a district judge, in making in a civil action an order not otherwise appealable under this section, shall be of the opinion that such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation, he shall so state in writing in such order. The Court of Appeals which would have jurisdiction of an appeal of such action may thereupon, in its discretion, permit an appeal to be taken from such order, if

[1] In their response, Plaintiffs indicated that they were not pursuing claims of strict liability for a manufacturing defect, leaving only claims of strict liability for a design defect and failure to warn.

[2] In 1996, the Pennsylvania Supreme Court applied comment k to bar strict liability failure to warn suits involving prescription drugs. *Hahn v. Richter*, 673 A.2d 888, 890 (Pa. 1996). However, the court has not extended this holding to cover prescription medical devices.

> application is made to it within ten days after the entry of the order: Provided, however, that application for an appeal hereunder shall not stay proceedings in the district court unless the district judge or the Court of Appeals or a judge thereof shall so order.

28 U.S.C. § 1292(b). The decision is within the Court's discretion and "the burden is on the movant to demonstrate that a 1292(b) appeal is warranted." *Orson, Inc. v. Miramax Film Corp.*, 867 F. Supp. 319, 320 (E.D. Pa. 1994) (citation omitted).

Thus, the issues to be determined with respect to Coloplast's pending motion are: 1) whether the order involves a controlling question of law; 2) as to which there is substantial ground for difference of opinion; and 3) whether an immediate appeal from the order may materially advance the ultimate termination of the litigation. *Katz v. Carte Blanche Corp*., 496 F.2d 747, 754 (3d Cir. 1973) (citation omitted). The moving party must demonstrate that all of the elements are met, *Katz, id.*, and even then, the court should be "mindful of the policy against piecemeal appeals." *Orson,* 867 F. Supp. at 321.

Substantial Ground for Difference of Opinion on a Controlling Question of Law

A controlling question of law is one that "would result in a reversal of a judgment after final hearing." *Katz*, 496 F.2d at 755. There is little doubt that the issue of whether Plaintiffs may proceed with their strict liability claims is a controlling question of law in this case. Coloplast argues that there is a substantial ground for difference of opinion on this controlling question of law because while some federal district courts have reached the same conclusion as this court, thirty-three other federal district court decisions conversely have held that strict liability claims involving prescription medical devices are barred by comment k of § 402A.[3]

[3] This is an oversimplification because a number of cases have allowed strict liability manufacturing defect claims (which were not at issue in *Hahn*) to be asserted against prescription medical devices. *See, e.g., Smith v. Howmedica Osteonics Corp.*, 251 F. Supp. 3d 844, 850 (E.D. Pa. 2017) (citing cases); *Wagner v. Kimberly-Clark Corp.*, 225 F. Supp. 3d 311, 317-18 (E.D.

Coloplast contends that the holding by the Pennsylvania Supreme Court in *Tincher* does not compel a different result because the case did not involve prescription medical devices, did not overrule *Hahn* or *Lance* and in fact, acknowledged *Hahn*'s application of comment k to prescription drugs.[4] They observe that the Pennsylvania Superior Court has already held that comment k applies to prescription medical devices. *See Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. 2006).

In what Coloplast describes as dicta, Plaintiffs assert that the Pennsylvania Supreme Court in *Tincher* noted that courts should not engage in immunizing whole categories of products from strict liability, a process that instead should be undertaken by the General Assembly. Further, they point out that an interlocutory appeal to the Third Circuit would not resolve this issue, but only result a prediction by the Court of Appeals about how the Pennsylvania Supreme Court would decide.[5] Moreover, they note that there are already two cases on appeal at the Pennsylvania Superior Court that will reach the issue long before the Court of Appeals would do

---

Pa. 2016).

[4] However, there is no substantial ground for difference of opinion about the presumption that under Pennsylvania law, products can be the subject of strict products liability suits (ECF No. 99 at 7). That is what the Pennsylvania Supreme Court stated in *Tincher*. The issue in this case is whether prescription medical devices such as the Aris are an exception to this presumption, as prescription drugs have been found to be.

[5] Plaintiffs cite no authority to support the contention that a split of opinion among federal courts on an issue of state law cannot constitute a "difference of opinion" because the court of appeals will only be making a prediction as to what the state supreme court would hold. Regardless of whether the difference of opinion arises within federal or state court decisions, the court of appeals is always called upon to make this prediction, and it can seek guidance from the state supreme court. *See Rosenberg v. C.R. Bard, Inc.*, 387 F. Supp. 3d 572, 581-82 & n.5 (E.D. Pa. 2019) (certifying the issue of whether strict liability manufacturing defect claims fall within comment k to the Third Circuit and suggesting that the Third Circuit certify the issue to the Pennsylvania Supreme Court). The *Rosenberg* court subsequently denied certification because no party made an application in the Court of Appeals. 2019 WL 4126485 (E.D. Pa. Aug. 12, 2019).

so in this case.[6]

Plaintiffs further contend that the *Creazzo* court, which conducted no policy analysis, did not issue a decision regarding categories of products. Rather, it found that the device at issue (an implantable neurological electrical pulse generator used to alleviate pain) was indistinguishable from the prescription drug at issue in *Hahn* and was thus "unavoidably unsafe." Moreover, Plaintiffs argue, *Creazzo* was issued before more recent Pennsylvania Supreme Court cases that would reject a categorical decision.

Having considered the parties' arguments, the Court concludes that Coloplast has demonstrated that there is a substantial basis for a difference of opinion on a controlling question of law. The majority of federal district court cases have concluded that strict liability claims involving prescription medical devices (particularly those involving theories of failure to warn and design defects) are barred by comment k, while three cases[7] (including this one) have concluded otherwise. The Pennsylvania Superior Court has held that such claims are barred, albeit in an opinion that has little discussion of the issue, has been heavily criticized and may no longer be an accurate prediction of how the Pennsylvania Supreme Court would address the issue in the light of its more recent decisions.

The Pennsylvania Supreme Court has not explicitly addressed the issue, although various statements in *Tincher* strongly suggest that the court would not welcome a categorical approach to strict liability claims based on an expansion of its holding in *Hahn* (which the court cautioned

[6] *See Ebaugh v. Ethicon, Inc.*, No. 463 EDA 2018 (Pa. Super.); *Emmet v. Ethicon, Inc.*, No. 1078 EDA 2019 (Pa. Super.). The *Ebaugh* case was originally scheduled for oral argument on April 21 and 22, 2020, but it has been postponed because of the COVID-19 pandemic.

[7] Since the Court's decision in this case, a fourth decision has rejected Coloplast's argument. *See James v. United States*, 2020 WL 1624883 (E.D. Pa. Apr. 2, 2020).

against using as a basis for extrapolation in *Lance*).[8] This Court has predicted that the Pennsylvania Supreme Court would reject Coloplast's position, but did not hold that the court resolved the issue in *Tincher*. Finally, Plaintiffs cite no authority to support the contention that more advanced but unresolved appeals in other cases have any bearing on whether a substantial ground for difference of opinion is presented in this case.

Would Immediate Appeal Materially Advance the Litigation

"In determining whether certification will materially advance the ultimate termination of the litigation, a district court is to examine whether an immediate appeal would (1) eliminate the need for trial, (2) eliminate complex issues so as to simplify the trial, or (3) eliminate issues to make discovery easier and less costly." *Orson*, 867 F. Supp. at 322.

In this case, an appeal would not eliminate the need for trial and discovery has already concluded. Thus, the only basis for meeting this factor would be to eliminate complex issues in order to simply the trial. Coloplast contends that certification of this issue to the Court of Appeals would simplify the trial by the elimination of complex issues, citing *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 553, 600 (E.D. Pa. 2008). However, as Plaintiffs note, *Knipe* involved an issue of federal preemption that is not comparable to the issue presented in this case, and a reversal would have meant the entire case had to be dismissed. In addition, the *Knipe* court stated that: "[w]here discovery is complete and the case is ready for trial an interlocutory appeal can hardly advance the ultimate termination of the litigation." *Id.*

[8] Coloplast argues that prescription medical devices were not at issue in *Tincher*, an argument that a few courts have found persuasive. *See Kohn v. Ethicon, Inc.*, 2020 WL 733126, at *4 (E.D. Pa. Feb. 13, 2020) (stating that *Tincher* "dealt with steel tubing"). In *Tincher*, the court addressed important issues of how strict liability claims should be treated under Pennsylvania law, including the issue of whether the court would adopt the Restatement (Third) of Torts § 402A. The fact that the product at issue in the case was steel tubing is barely mentioned. Thus, this Court respectfully disagrees with the suggestion that *Tincher* is distinguishable on that basis.

The Court concludes that an interlocutory appeal will not materially advance the litigation in this case. Even though trial is not imminent, discovery has concluded, Coloplast's motion for summary judgment has been decided and all other pretrial matters, including a date for the commencement of a jury trial, will be scheduled shortly. As Plaintiffs note, an interlocutory appeal will merely result in a delay of the resolution of this case, and even if the appeal was successful, would not result in the dismissal of the entire case as both the negligence and strict liability claims involve allegations of design defect and failure to warn. The trial in this case will involve the same witnesses, documents and theories of recovery. Thus, no "complex issue" would be eliminated and Coloplast would be faced with the same financial exposure in terms of damages. Coloplast also argues that the jury charge would have to be altered if claims of strict liability were eliminated. The fact that the jury charge might be impacted does not, in and of itself, present an exceptional case that would overcome the general preference for avoiding piecemeal appeals. *See also Schrecengost v. Coloplast Corp.*, 2019 WL 7499923 (W.D. Pa. Dec. 19, 2019) (denying the request for interlocutory appeal of this issue on the ground that it would not materially advance the litigation but rather, result in delay).

III. Conclusion

Therefore, for the reasons cited above, Defendants' Motion for Certification of Interlocutory Appeal (ECF No. 98) will be denied.

An appropriate order follows.

Dated: April 21, 2020

PATRICIA L. DODGE
United States Magistrate Judge